percentage of both high and low density polyethylene may be used in the catheter. Applicants have now amended Claim 39 to clarify this intended meaning and request that this objection now be withdrawn.

The Examiner also objects to the term "central opening" in line 12 of Claim 19. This is a typographical error. Applicants have now amended line 12 of Claim 19 to recite "the central opening" which has a clear antecedent basis in line 4 of the claim. Accordingly, it is requested that this objection be withdrawn.

The Examiner also objects to the limitation of "a patient" in line 4 of Claim 22. While Applicants disagree with this objection (the term is really part of the phrase "the body of a patient" which has an antecedent basis in Claim 21), in order to advance the prosecution of this application, Applicants has amended this term to be "the body of the patient." It is respectfully submitted that this overcomes the objection to this claim, and it is requested that the objection be withdrawn.

Finally, the Examiner objects to Claim 40. As this claim is being canceled in order to advance the prosecution of this application, this objection is now moot.

Accordingly, it is requested that the §112 rejections now be withdrawn.

Claim Rejections - 35 USC §102

The Examiner also rejects Claim 19 under 35 USC 102(e) as being anticipated by Waksman et al. This rejection is respectfully traversed.

Claim 19 is directed to a catheter for use in an intraluminal treatment system including a transfer device with a central opening for receiving the catheter. The claim requires the catheter to have an integral connector with at least one detent for securing the connector in the central opening of the transfer device, with the detent being manually actuable to release the catheter from the

central opening. This feature is shown for example in Fig. 41C and described on page 33, lns. 20-33 of the specification of the present application as follows:

> The central plug portion 386 of the connector 364 includes two integral, radially-opposed cantilever arms 396 that are connected to the distal end of the central plug 386 and extend axially along, but spaced away from, the central plug portion. The proximal ends of the arms 396 include transverse detent tabs 398 that, when the connector is inserted into the transfer device, snap into contact with a protecting shoulder 400 (Fig. 32C) in the distal end of the transfer device, thus securing the connector in place. To disengage the connector from the transfer device, the cantilever arms 396 must be depressed radially inwardly to allow the detent tabs 398 to clear the shoulder 400. Simultaneously, the release button 318 must be depressed to disengage the release switch 358 from the connector.

See also Fig. 58A and page 55, lns. 31 et seq., which illustrate and describe connector 588 with detents 626.

The Examiner, however, states that the limitations in Claim 19 read on a catheter with at least one detent on the proximal end while the rest of the claim defines functionality and Waksman's apparatus is capable of performing the functions recited in the claim.

Waksman, however, does not disclose or suggest a detent. As is clear from the specification and Claim 19 of the present application, a detent must "secure" (i.e. lock) the connector in the central opening of the transfer device. See e.g. American Heritage Dictionary of the English Language, 4th Ed. 2000 (copy attached) which states that a detent is "a catch or lever that locks the movement of one part of a mechanism."

In contrast, Waksman discloses a specially keyed fitting to prevent the inadvertent attachment of the fitting or body to other catheters on the market which are not specifically designed to receive the treating elements and/or prevent the treating elements from being released into the body. See col. 13, lns. 47-51 of Waksman. More specifically, the Waksman device is for delivery of a treating element, such as a radiation source, to a desired site in a patient. It is important in this

patent that the treating element remains within the Waksman device and is not released into the body at the distal end of the catheter. Many catheters on the market, however, are made with openings on the distal end to provide access to the desired treatment spot. When using the treating elements of the Waksman device, one wants to be sure that the proximal end of the Waksman device is connected to a catheter which does not have an opening to the body on the distal end. Accordingly, a specially keyed fitting is provided so that the proximal end can only be attached to a specific catheter, one which has no opening to the body on the distal end. There is nothing, however, in Waksman about the keyed fitting locking the catheter in place. This is not a concern in the patent. Rather, the keyed fitting is for preventing inadvertent attachment. Hence, Waksman does not disclose or suggest a detent.

Since Waksman does not disclose or suggest this claimed feature of Claim 19, it cannot anticipate the claim, and Claim 19 is patentable thereover. Accordingly, it is requested that this rejection be withdrawn.

Claim Rejections - 35 USC §103

Rejection of Claims 21-22

The Examiner rejects Claims 21-22 under 35 USC §103 over Yock and further in view of Bennett et al. This rejection is also traversed.

Claim 21 is directed to a catheter for use in a system for intraluminal treatment of a selected site in a body where the catheter has first and second lumens extending between the proximal and distal ends and communicating at the distal ends. One of the reasons for this feature is to keep the treating element within the catheter.

Such a feature is not disclosed or suggested by Yock or Bennett (which has not been cited for this feature). As shown in the figures in Yock, none of the lumens communicate with each other at the distal ends. Further, Yock does not disclose a treating element movable by means of pressurized fluid, as required in Claim 21. Instead, Yock is directed to a balloon dilation catheter which has a radiopaque contrast liquid to fill the balloon. Hence, the cited references do not disclose or suggest this feature, and Claim 21 is patentable thereover.

Claim 22 is dependent from Claim 21 (and therefore patentable for the reasons discussed above) and calls for a radiopaque marker located within the first lumen (which receives the treating element) at the distal end of the catheter. This is described for example in the specification on page 57 at lns. 13-19, which describe an intraluminal connector 646 made of platinum/iridium so as to be visible under flouroscopy. See also Fig. 58C. Claim 22 also requires the radiopaque marker to provide a fluid flow path between the first and second lumens.

Neither cited reference disclose or suggest either of these features. For example, the radiopaque contrast liquid in Yock is for filling the balloon; this liquid is not a radiopaque marker for aligning the distal end and the treating element with a selected spot in the body as required in Claim 22. Nor can this fluid be a fluid path between the first and second lumen, as also required in the claim. Hence, this claim is also not disclosed or suggested by Yock (or Bennett) and is patentable thereover.

Therefore, it is requested that the rejection of Claims 21 and 22 be withdrawn.

Rejection of Claim 20

The Examiner also rejects dependent Claim 20 under 35 USC §103 as being patentable over Waksman et al. and further in view of Bressler et al. This rejection is also traversed.

As this claim is dependent on independent Claim 19, Claim 20 is patentable for at least the reasons described above for Claim 19.

Claim 20 is also patentable for additional reasons. In particular, Claim 20 requires the detent on the catheter to comprise the cantilever arm axially extending from the connector. Such a structure is not disclosed or suggested by either cited reference. As discussed *supra*, Waksman discloses a keyed fitting, while Bressler discloses a needle assembly having a single-handedly activable needle barrier.

Applicants do not see how these references can be combined to arrive at the claimed invention.

Bressler discloses a needle guard or barrier that has an elongated arm 37 that prevents unintended needle sticks. The Examiner proposes combining this reference with the catheter of Waksman. The Examiner alleges that the combination of these references is not hindsight reconstruction because Bressler states that it is important for the caregiver to know when the device has been locked in. Applicants respectfully submits that this is an insufficient teaching to combine these references.

As the Federal Circuit has held on numerous occasions, "[w]hen a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references." Ecolochem, Inc. v. Southern California Edison Company, 56 USPQ2d 1065, 1073 (Fed. Cir. 2000). "Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight." Id. Such hindsight reconstruction is improper, and a rejection based thereon should be withdrawn. Id. at 1072-1076.

In this case, the Examiner has picked selective pieces from the references to arrive at the claimed invention. For example, the claimed invention is directed to a catheter and a transfer device having a central opening for receiving the catheter and propelling the treatment element in to the lumen in the catheter. A connector with a detent is used to secure the catheter and the transfer device. Waksman discloses a catheter with a keyed feature and not the required detent. Therefore, the Examiner went out and found a cantilever arm assembly, not on a catheter, or even on a needle to keep it secured to a proximal device.[1] Instead, the Examiner has found a cantilever assembly on an appendage, a needle guard, to a needle apparatus and proposes to substitute this onto the Waksman device, not on an appendage thereon but on the catheter connection. Applicants respectfully submit that this is simply too far a stretch. There is no teaching or suggestion in either reference to make such a substitution, as required under the law. Instead, the only basis for such a substitution would be by using the claimed invention as a blue print.

As this is unacceptable hindsight reconstruction, Claim 22 is patentable, and it is requested that the rejection of this claim be withdrawn.

Rejection of Claim 39

The Examiner rejects Claim 39 (and apparently Claim 38) under 35 USC §103 as being unpatentable over Waksman et al. and further in view of Sung et al. or Littmann et al.

Claim 38 is directed to a catheter for use in an intraluminal treatment system. The catheter has three lumens, one of which is sized to receive a guidewire. Importantly, the distal end of this lumen is required to have a lining that resists damage from the guidewire as the catheter is delivered

[1]Applicants do not admit that such a substitution is acceptable.

over the guidewire to the treatment site. This is described for example in the specification on page 36, lines 21-26 and is shown in Fig. 42C. As explained therein, such a lining is of a sufficient durometer to resist the guidewire from damaging the distal end of the lumen. Applicants can find no disclosure of such a lining in the cited references. Accordingly, the apparent rejection of Claim 38 should be withdrawn.

Claim 39 is dependent from Claim 38 and requires the guidewire lumen lining to comprise a high density polyethylene and a low density polyethylene. Based on the comments in the §112 rejection, Applicants do not believe that the Examiner understood this claim and have amended this claim to make this feature clear. The Examiner rejects Claim 39 over Waksman in view of Sung and Littman. The Examiner states that these references disclose utilizing a lining made from polyethylene, citing col. 6, lns. 25-30 of Sung. However, the claimed feature is not a polyethylene lining but a lining of a polyethylene blend of a high density polyethylene and a low density polyethylene. Further, the cited passage from Sung does not discuss making a lumen resistant to damage but instead discusses making it "lubrious". Therefore, as this feature is not disclosed or suggested by the cited references, Claim 39 is patentable thereover, and it is requested that the rejection be withdrawn.

Rejection of Claim 40

Finally, the Examiner rejects Claim 40 under 35 USC §103 as being unpatentable over Waksman et al and further in view of Bigham or Dinh or Apple et al. In order to advance the prosecution of this application, Applicants have canceled Claim 40, rendering this rejection moot.

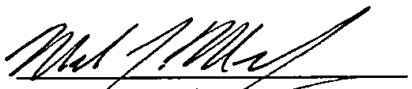
CONCLUSION

Therefore, for at least the above-stated reasons, the present application is now in an allowable condition and should be allowed.

Please charge our deposit account 50/1039 for any further fee for this amendment.

Favorable reconsideration is earnestly solicited.

Respectfully submitted,



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Marked-up copy of the claims as amended:

IN THE CLAIMS:

Please amend the claims as follows:

19 (Amended). In a catheter having a proximal end and a distal end useable in a system for intraluminal treatment of a selected site in a body of a patient including a transfer device having a central opening for receiving the catheter and for storing at least one treatment element and propelling the treatment element into a lumen in the catheter, the improvement comprising:

a connector integral with the proximal end of the catheter including at least one detent for securing said connector in the central opening of the transfer device, said detent being manually actuable to release the catheter from the central opening of the transfer device.

22. (Twice Amended) The catheter of Claim 21 further comprising at least one radiopaque marker for aligning said distal end and the at least one treating element with the selected site of the body of [a] the patient, said radiopaque marker being located within said first lumen at said distal end and providing a fluid flow path between said first and second lumen.

39 (Amended). The catheter of Claim 38 wherein said lining comprises a polyethylene blend of a high density polyethylene and a low density polyethylene.

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detent

SYLLABICATION: de·tent

PRONUNCIATION: dĭ-tĕnt'

NOUN: A catch or lever that locks the movement of one part of a mechanism.

ETYMOLOGY: French *détente*, a loosening, from Old French *destente*, from feminine past participle of *destendre*, to release : *des-*, de- + *tendre*, to stretch (from Latin *tendere*; see **ten-** in Appendix I).

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